APR 1 0 2006

K060755

510(k) Summary - Elecsys Vitamin B_{12} Test System

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, contact

Roche Diagnostics
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3532

Contact person: Randy Johnson

Date prepared: March 20, 2006

Device name

Proprietary name:	(1) Elecsys Vitamin B_{12} Immunoassay (2) Elecsys Vitamin B_{12} CalSet II (3) Elecsys Vitamin B_{12} CalCheck
Common name:	(1) Vitamin B_{12} Assay (2) Vitamin B_{12} CalSet (3) Vitamin B_{12} CalCheck
Classification name:	(1) Radioassay, Vitamin B_{12} (2) Calibrator, Secondary (3) Single (specified) analyte controls (assayed and unassayed).

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510(k) Summary - Elecsys Vitamin B_{12} Test System, Continued

Device description

(1) The Elecsys Vitamin B_{12} Assay employs a competitive test principle using intrinsic factor specific for Vitamin B_{12}. Vitamin B_{12} in the sample competes with the added Vitamin B_{12} labeled with biotin for the binding sites on the ruthenium-labeled intrinsic factor complex. Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent barcode.

(2) The Elecsys Vitamin B_{12} CalSet II is a lyophilized product consisting of human serum with added Vitamin B_{12} in two concentration ranges. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

(3) The Elecsys Vitamin B_{12} CalCheck is a lyophilized product consisting of human serum with added Vitamin B_{12}. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

Intended use

(1) The Vitamin B_{12} assay is a Binding assay for the in vitro quantitative determination of vitamin B_{12} in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.

(2) Elecsys Vitamin B_{12} CalSet II is used for calibrating the quantitative Elecsys Vitamin B_{12} assay on the Elecsys 2010 and MODULAR ANALYTICS E170 immunoassay analyzers.

(3) For use in the verification of the calibration established by the Elecsys Vitamin B_{12} reagent on Elecsys 2010 and MODULAR ANALYTICS E170 immunoassay analyzers.

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510(k) Summary - Elecsys Vitamin B_{12} Test System, Continued

Predicate device

The Elecsys Vitamin B_{12} Test System is equivalent to other devices legally marketed in the United States. We claim equivalence for the following items:

For the Vitamin B_{12} assay and the Vitamin B_{12} CalSet II:

- The original Elecsys Vitamin B_{12} on the Elecsys 2010 was cleared under K973702.
- In 2001 under K961481/A003, the MODULAR ANALYTICS E170 analyzer was acknowledged by FDA.

For the Vitamin B_{12} CalCheck:

- The original Elecsys Vitamin B_{12} CalCheck was cleared under K974383.

510(k) Summary - Elecsys Vitamin B_{12} Test System, Continued

Device comparison (Reagents)

The table below compares the Elecsys Vitamin B_{12} (K973702) and the Elecsys Vitamin B_{12} (modified device).

Substantial equivalence – similarities

Topic	Elecsys Vitamin B_{12} (K973702)	Elecsys Vitamin B_{12} (Modified Device)
REAGENTS		
Intended use	Binding assay for the in vitro quantitative determination of vitamin B_{12} in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010/2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.	Binding assay for the in vitro quantitative determination of vitamin B_{12} in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.
Assay Protocol	Competitive assay	Same
Detection Protocol	Electrochemiluminescence immunoassay	Same
Measuring range	30 -2,000 pg/mL	Same
Analytical sensitivity (lower detection limit)	30 pg/mL	Same

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510(k) Summary - Elecsys Vitamin B_{12} Test System, Continued

Device comparison (Calibrators)

The table below compares the Elecsys Vitamin B_{12} CalSet (K973702) and the Elecsys Vitamin B_{12} CalSet II (modified device).

Substantial equivalence – similarities

Topic	Elecsys Vitamin B_{12} CalSet (K973702)	Elecsys Vitamin B_{12} CalSet II (Modified Device)
CALIBRATORS		
Intended use	Elecsys B_{12} CalSet is used for calibrating the quantitative Elecsys B_{12} assay on the Elecsys 2010 immunoassay system.	Elecsys Vitamin B_{12} CalSet II is used for calibrating the quantitative Elecsys Vitamin B_{12} assay on the Elecsys 2010 and MODULAR ANALYTICS E170 immunoassay analyzers.
Levels	Two	Same

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510(k) Summary - Elecsys Vitamin B_{12} Test System, Continued

Device comparison (CalCheck)

The table below compares the Elecsys Vitamin B_{12} CalCheck (K974383) and the Elecsys Vitamin B_{12} CalCheck (modified device).

Substantial equivalence – similarities

Topic	Elecsys Vitamin B_{12} CalCheck (K974383)	Elecsys Vitamin B_{12} CalCheck (Modified Device)
CALIBRATION VERIFICATION		
Intended use	For use in the verification of the calibration established by the Elecsys Vitamin B_{12} reagent and CalSet on the Elecsys 2010 immunoassay analyzer.	For use in the verification of the calibration established by the Elecsys Vitamin B_{12} reagent on Elecsys 2010 and MODULAR ANALYTICS E170 immunoassay analyzers.
Levels	Three	Same

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510(k) Summary - Elecsys Vitamin B_{12} Test System, Continued

Device comparison (Reagents)

The table below compares the differences between the Elecsys Vitamin B_{12} (K973702) and the Elecsys Vitamin B_{12} (modified device).

Substantial equivalence – differences

Topic	Elecsys Vitamin B_{12} (K973702)	Elecsys Vitamin B_{12} (Modified Device)
	REAGENTS	
Quality control	Elecsys PreciControl Universal	Elecsys PreciControl Anemia 1, 2 and 3
Formulation (PT2)	Composition of PT2: 36 g/L NaOH (0.9 M)	Composition of PT2: 40 g/L NaOH (1.0M)
Specimen collection and preparation	No additional statement was provided.	A note was added to this section: Note: Samples with extremely high total protein concentrations (e.g. patients suffering from Waldenstrom's macroglulinemia) are not suitable for use in this assay, since they may lead to the formation of protein gel in the assay cup. Processing protein gel may cause a run abort. The critical protein is dependent upon the individual sample composition. The formation of protein gel was seen in samples (spiked with human IgG or human serum albumin) having a total protein concentration of > 160 g/L.

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510(k) Summary - Elecsys Vitamin B_{12} Test System, Continued

Device comparison (Reagents), continued

The table below compares the differences between the Elecsys Vitamin B_{12} (K973702) and the Elecsys Vitamin B_{12} (modified device).

Substantial equivalence – differences

Topic	Elecsys Vitamin B_{12} (K973702)	Elecsys Vitamin B_{12} (Modified Device)
	REAGENTS	
Precision	*Elecsys 2010* Within-Run: Human Serum 1: 6.9% 203 pg/mL Human Serum 2: 4.2% 481 pg/mL Human Serum 3: 2.7% 1,499 pg/mL Control 1: 2.8% 1,119 pg/mL Control 2: 4.3% 471 pg/mL Total: Human Serum 1: 7.6% 203 pg/mL Human Serum 2: 4.4% 481 pg/mL Human Serum 3: 3.2% 1,499 pg/mL Control 1: 3.2% 1,119 pg/mL Control 2: 4.6% 471 pg/mL *MODULAR ANALYTICS E170* Within-Run: Human Serum 1: 2.4% 155 pg/mL Human Serum 2: 2.8% 359 pg/mL Human Serum 3: 0.6% 1,162 pg/mL PreciControl U1: 0.9% 667 pg/mL PreciControl U2: 4.3% 399 pg/mL Total: Human Serum 1: 6.1% 157 pg/mL Human Serum 2: 3.6% 349 pg/mL Human Serum 3: 2.2% 1,128 pg/mL PreciControl 1: 2.8% 671 pg/mL PreciControl 2: 4.2% 391 pg/mL	*Elecsys 2010* Within-Run: HS 1: 8.7% 232 pg/mL HS 2: 4.4% 818 pg/mL HS 3: 3.0% 1,245 pg/mL PCA 1: 8.3% 226 pg/mL PCA 2: 4.0% 610 pg/mL PCA 3: 3.1% 1,369 pg/mL Total: HS 1: 9.5% 232 pg/mL HS 2: 5.1% 818 pg/mL HS 3: 3.7% 1,245 pg/mL PCA 1: 8.0% 226 pg/mL PCA 2: 5.2% 610 pg/mL PCA 3: 3.4% 1,369 pg/mL *MODULAR ANALYTICS E170* Within-Run: HS 1: 1.2% 267 pg/mL HS 2: 2.9% 887 pg/mL HS 3: 1.5% 1,308 pg/mL PCA 1: 1.7% 308 pg/mL PCA 2: 1.0% 710 pg/mL PCA 3: 0.8% 1,524 pg/mL Total: HS 1: 8.4% 269 pg/mL HS 2: 3.3% 853 pg/mL HS 3: 2.5% 1,261 pg/mL PCA 1: 7.5% 239 pg/mL PCA 2: 3.7% 658 pg/mL PCA 3: 2.4% 1,415 pg/mL

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510(k) Summary - Elecsys Vitamin B_{12} Test System, Continued

Device comparison (Reagents), continued

The table below compares the differences between the Elecsys Vitamin B_{12} (K973702) and the Elecsys Vitamin B_{12} (modified device).

Substantial equivalence – differences

Topic	Elecsys Vitamin B_{12} (K973702)	Elecsys Vitamin B_{12} (Modified Device)
	REAGENTS	
Method comparison	*Comparison of the Elecsys Vitamin B_{12} (y) with a commercially available radiobinding Vitamin B_{12} assay (x):* N = 345 Passing Bablok: y = -9.2 + 1.06x r = 0.977 SD(md68) = 45.7 Linear regression: y = 7.4 +1.02x r = 0.977 Sy.x = 75.5 Sample concentrations range: 30 – 1,798 pg/mL	*Comparison of the Elecsys Vitamin B_{12} assay MODULAR ANALYTICS E170 calibrated with the Elecsys Vitamin B_{12} CalSet(x) versus the MODULAR ANALYTICS E170 calibrated with the Elecsys Vitamin B_{12} CalSet II (y):* N = 101 Passing Bablok: y = 0.982x – 0.018 r = 0.977 SD(md68) = 8.05 Linear regression: y = 0.968x + 5.77 r = 0.999 Sy.x = 9.63 Sample concentration range: 49 – 1,691 pg/mL

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Device comparison (Reagents), continued

The table below compares the differences between the Elecsys Vitamin B_{12} (K973702) and the Elecsys Vitamin B_{12} (modified device).

Substantial equivalence – differences

Topic	Elecsys Vitamin B_{12} (K973702)	Elecsys Vitamin B_{12} (Modified Device)
	REAGENTS	
Traceability	Elecsys Vitamin B_{12} has been calibrated against a commercially available radiobinding Vitamin B_{12} assay.	This method has been standardized against the Elecsys Vitamin B_{12} assay.
Stability	Unopened at 2 - 8°C:: Up to the stated expiration date After opening: 12 weeks at 2 - 8°C On E170/Elecsys 2010: 8 weeks	Unopened at 2 - 8°C:: Up to the stated expiration date After opening at 2 – 8°C: 12 weeks On Elecsys 2010: 5 weeks On MODULAR ANALYTICS E170: 5 weeks
Expected values	Normal range United States: 243 – 894 pg/mL Europe: 197 – 866 pg/mL	Normal range: United States: 211 – 946 pg/mL Europe: 191 – 663 pg/mL
Calibration verification	Not necessary. The analyzer's software automatically checks the validity of the curve and draws attention to any deviations.	Section deleted.

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510(k) Summary - Elecsys Vitamin B_{12} Test System, Continued

Device comparison (Calibrator)

The table below compares the differences between the Elecsys Vitamin B_{12} CalSet (K973702) and the Elecsys Vitamin B_{12} CalSet II (modified device).

Substantial equivalence – differences

Topic	Elecsys Vitamin B_{12} CalSet (K973702)	Elecsys Vitamin B_{12} CalSet II (Modified Device)
CALIBRATOR		
Platform	To be used on the Elecsys 2010 immunoassay analyzer.	To be used on Elecsys 2010 and the MODULAR ANALYTICS E170 immunoassay analyzers.
Matrix	Human serum albumin with added Vitamin B_{12}	Human serum with added Vitamin B_{12}
Storage form	Liquid	Lyophilized
Filling volume	1.5 mL	1.0 mL
Concentration ranges	Cal 1: approximately 100 pg/mL Cal 2: approximately 1,500 pg/mL	Cal 1: approximately 250 pg/mL Cal 2: approximately 1,500 pg/mL
Stability	Unopened at 2 - 8°C: Up to the stated expiration date After opening: 12 weeks at 2 - 8°C On the analyzer: Up to 5 hours in total	Unopened at 2 - 8°C: Up to the stated expiration date After reconstitution: At 2 - 8°C: 3 days At -20°C: 3 months (freeze only once) On the analyzer at 20 - 25°C: Use only once.
Traceability	None listed in the package insert.	The Elecsys Vitamin B_{12} assay (Cat. No. 04745736) has been standardized against the Elecsys Vitamin B_{12} assay (Cat. No. 11820753).

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510(k) Summary - Elecsys Vitamin B_{12} Test System, Continued

Device comparison (Calibration verification)

The table below compares the differences between the Elecsys Vitamin B_{12} CalCheck (K974383) and the Elecsys Vitamin B_{12} CalCheck (modified device).

Substantial equivalence – differences

Topic	Elecsys Vitamin B_{12} CalCheck (K974383)	Elecsys Vitamin B_{12} CalCheck (Modified Device)
CALIBRATION VERIFICATION		
Platform	To be used on the Elecsys 2010 immunoassay analyzer.	To be used on the Elecsys 2010 and the MODULAR ANALYTICS E170 immunoassay analyzer.
Matrix	Buffer matrix with added human serum albumin.	Human serum matrix
Storage	Liquid	Lyophilized
Fill Volume	1.9 mL	1.0 mL
Target concentration	Level 1: Approximately 150 pg/mL Level 2: Approximately 875 pg/mL Level 3: Approximately 1,600 pg/mL	Level 1: ≤ 300 pg/mL Level 2: Same Level 3: Same
Traceability	None listed in the package insert.	This method has been standardized against the Elecsys Vitamin B_{12} assay.
Stability	Store unopened at 2 - 8°C: Up to the printed expiration date on the bottle labels. Stability opened: 5 hours at 20-25°C	Store unopened at 2 - 8°C: Up to the printed expiration date on the bottles labels. Stability reconstituted: 4 hours at 20-25°C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 10 2006

Mr. Randy J. Johnson
M.T. (ASCP), Regulatory Affairs Consultant
Roche Diagnostics Corp.
9115 Hague Road
PO Box 50457
Indianapolis, IN 46250-0457

Re: k060755
Trade/Device Name: Elecsys Vitamin B_{12} Immunoassay, Calset II and Cacheck
Regulation Number: 21 CFR§862.1810
Regulation Name: Vitamin B_{12} test system
Regulatory Class: Class II
Product Code: CDD, JIT, JJX
Dated: March 20, 2006
Received: March 21, 2006

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060755

Device Name: Elecsys Vitamin B_{12} Assay

Indications For Use:

Binding assay for the in vitro quantitative determination of vitamin B_{12} in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.

A Vitamin B_{12} test system is a device intended to measure Vitamin B_{12} in serum, plasma. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060755

Indications for Use

510(k) Number (if known): K060755

Device Name: Elecsys Vitamin B_{12} CalSet II

Indications For Use:

Elecsys Vitamin B_{12} CalSet II is used for calibrating the quantitative Elecsys Vitamin B_{12} assay on the Elecsys 2010 and MODULAR ANALYTICS E170 immunoassay analyzers.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060755

Indications for Use

510(k) Number (if known): K060755

Device Name: Elecsys Vitamin B_{12} CalCheck

Indications For Use:

For use in the verification of the calibration established by the Elecsys Vitamin B_{12} reagent on Elecsys 2010 and MODULAR ANALYTICS E170 immunoassay analyzers.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060755